K000604

MAY 2 3 2000

510(k) Summary
Naturopathic Laboratories International, Inc.
Nature's Chemist Pain Relief Ointment and Therapeutic Ultrasound Coupling Agent

I. General Information on Submitter:

Name: Naturopathic Laboratories International, Inc.
Address: 12061 31st Court North
St. Petersburg, Florida 33716
Telephone: (727) 573-5522
Fax: (727) 572-6938
Name of Contact Person: Jan D. Knigge

Date Summary Prepared: February 16, 2000

II. General Information on Device

Name: Nature's Chemist Pain Relief Ointment

Classification Name: Ultrasound Diathermy for Applying Deep Heat, Coupling Agent

III. Predicate Device: Aquasonic 100 (K802146)

IV. Description of the Device:

The device is an over-the-counter external analgesic containing menthol in a lanolin base that may be used as a coupling agent for therapeutic ultrasound.

V. Intended Use:

For temporary relief of the minor pain and stiffness of arthritis, muscle aches and strains, and for use as a coupling agent for therapeutic ultrasound.

VI. Technological Characteristics of Device Compared to Predicate Device:

The technological characteristics of the two devices are similar with the exception of the formulation base (i.e., lanolin versus water) and the addition of an external analgesic active ingredient to the Nature's Chemist device (i.e., menthol).

VII. Summary of Clinical Data

A clinical study was performed to confirm that, when used as a coupling agent for therapeutic ultrasound, the Nature's Chemist device is as safe and effective as the predicate device (i.e., does not adversely affect the effectiveness of therapeutic ultrasound devices). The effectiveness of the ultrasound therapy was evaluated using a thermocouple placed under the subcutaneous layer. The study compared the effectiveness of the following coupling agents: (1) a mixture of

Nature's Chemist and the predicate device; (2) the predicate device alone; and (3) a mixture of another external analgesic and the predicate device. The subjects in a fourth study group had a mixture of Nature's Chemist and the predicate device applied to them, but were treated with an ultrasound transducer that was not turned on. All three study groups that received active ultrasound therapy demonstrated similar tissue heating effects. As predicated, the four study group showed significantly less tissue heating. Therefore, it was concluded that Nature's Chemist Pain Relief Ointment has an effect on therapeutic ultrasound that is identical to that of the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2000

Ms. Emalee G. Murphy
Naturopathic Laboratories International, Inc.
c/o McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, D.C. 200006-1108

Re: K000604
Trade Name: Nature's Chemist Therapeutic Ultrasound Coupling Agent
Regulatory Class: II
Product Code: IMI
Dated: February 23, 2000
Received: February 23, 2000

Dear Ms. Murphy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K000604

Device Name: Nature's Chemist Pain Relief Ointment and Therapeutic Ultrasound Coupling Agent

Indications for Use:

For use as a coupling agent for therapeutic ultrasound.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

Donna Lachman
(Division Sign-Off)
Division [illegible] Devices
510(k) Number K000604